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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/022,481	12/18/2001	Miquel Sales Amill	INL-048	3281
22832 7590 07/09/2008 Kirkpatrick & Lockhart Preston Gates Ellis LLP (FORMERLY KIRKPATRICK & LOCKHART NICHOLSON GRAHAM) STATE STREET FINANCIAL CENTER One Lincoln Street BOSTON, MA 02111-2950				
EXAMINER FOSTER, CHRISTINE E				
ART UNIT 1641		PAPER NUMBER		
NOTIFICATION DATE 07/09/2008		DELIVERY MODE ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

**Advisory Action  
Before the Filing of an Appeal Brief**

**Application No.**

10/022,481

**Applicant(s)**

SALES AMILL ET AL.

**Examiner**

Christine Foster

**Art Unit**

1641

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 16 June 2008 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.  
b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.  
Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**NOTICE OF APPEAL**

2. ☐ The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

**AMENDMENTS**

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);  
(b) ☐ They raise the issue of new matter (see NOTE below);  
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.  
NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).

5. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.

6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_

Claim(s) objected to: \_\_\_\_\_

Claim(s) rejected: 1,3,5-8,10-18,22,32,34 and 35

Claim(s) withdrawn from consideration: \_\_\_\_\_

**AFFIDAVIT OR OTHER EVIDENCE**

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).

9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).

10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

**REQUEST FOR RECONSIDERATION/OTHER**

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.

12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). \_\_\_\_\_

13. ☐ Other: \_\_\_\_\_

/Long V Le/  
Supervisory Patent Examiner, Art Unit 1641

Continuation of 5. Applicant's reply has overcome the following rejection(s): (1) the rejection of claim 17 under 112, 1st paragraph; (2) the rejections of claims 1 and 22 under 112, 2nd paragraph; and (3) the objections to claims 14-15 and 17.

Continuation of 11, does NOT place the application in condition for allowance because:

With respect to the rejections under 35 USC 112, 1<sup>st</sup> paragraph, Applicant's arguments have been fully considered but are not persuasive for reasons of record. Applicant points to Example 4 of the Written Description Training Materials and argues that the disclosure of a single nucleic acid sequence sufficiently describes a claimed invention comprising that nucleic acid sequence (Reply, pages 6-7). However, the facts of the instant case differ from those in Example 4 because here, the specification and claims as originally filed disclose only a species and do not even suggest or introduce the concept of the genus that is presented in the amended claims. In particular, although the specification discloses a first member that "is" protein S, there is no suggestion or direction to the genus of first members that "comprise" protein S in addition to other amino acids or elements, as now claimed in the amended claims. Similarly, while C4BP per se is disclosed in the specification, the concept of the genus of members that "comprise" C4BP is not introduced. Moreover, in regards to the instant method claims, there is no suggestion in the specification to use a second member that "comprises" C4BP in a method to detect an unbound form of a first member that "comprises" protein S. Although first and second members are discussed generally, and exemplified as being protein S and C4BP, respectively, there is no introduction of the genus first and second members that "comprise" each of these species. The Examiner maintains that this use of open transitional language in the amended claims, which was not present in the specification as originally filed, represents new matter.

Applicant further argues that the specification teaches methods that include proteins, namely C4BP and Protein S, and that a person of ordinary skill in the art would be able to readily predict and visualize other proteins that read on the claimed invention. This is not found persuasive because as discussed above, there is no disclosure in the specification of members that "comprise" protein S or C4BP in addition to other amino acids or elements and thus no introduction of the genera now claimed.

Applicant further argues that support for particles comprising at least latex can be found in the specification as originally filed; however, the Examiner was unable to find support where indicated since the specification does not employ open transitional language in referring to latex particles but only discusses particles made of latex per se. Although the use of conjugates and/or derivatives of proteins is discussed at [0063] as noted by Applicant, the instant claims are not limited to conjugates or derivatives. Furthermore, conjugates or derivatives of binding members are discussed for use as reagents used to detect the analyte, but there is no direction to detect conjugates or derivatives as analytes. In particular, the indicated passages do not disclose the concept of detecting analytes that "comprise" unbound protein S.

With respect to the rejections under 35 USC 103 as being unpatentable over David et al. in view of Giri et al., Applicant's arguments (Reply, pages 10-11) were previously advanced in the Reply of 1/24/08 and are not persuasive for reasons of record (see the previous Office action at pages 21-24).

With respect to the rejections of claims 14-17 under 35 USC 103 as being unpatentable over David et al. in view of Giri et al. and Mischak et al., Applicant's arguments (Reply, page 12) were previously advanced in the Reply of 1/24/08 and are not persuasive for reasons of record (see the previous Office action at page 24).

With respect to the rejections of claim 35 under 35 USC 103 as being unpatentable over David et al. in view of Giri et al. and Cambiaso et al., Applicant's arguments (Reply, pages 12-13) were previously advanced in the Reply of 1/24/08 and are not persuasive for reasons of record (see the previous Office action at pages 24-25).

Applicant does not separately argue the limitations of dependent claim 13.

With respect to the non-statutory obviousness-type double patenting rejections, Applicant correctly notes that a double patenting rejection can be overcome by filing a terminal disclaimer (Reply, pages 8-9). However, the rejections are maintained for reasons of record because no terminal disclaimer has yet been made of record.